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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|--------------------------|----------------------|---------------------|------------------|--|
| 10/798,023 | 03/11/2004 | Stefan Petersson | PN0103 | 6027 | |
| Amersham Hea | 7590 03/21/200 lth, Inc. | EXAMINER | | | |
| IP Department 101 Camegie Center Princeton, NJ 08540 | | | LEACH, CRYSTAL I | | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | | 3737 | |
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| | | | MAIL DATE | DELIVERY MODE | |
| | | | 03/21/2008 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | | |
|--|---|--------------------|--|--|--|--|--|
| | 10/798,023 | PETERSSON ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | CRYSTAL I. LEACH | 3737 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 8/25/ | 2006. | | | | | | |
| | action is non-final. | | | | | | |
| <i>,</i> — | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1,4-11 and 13-15</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>1,4-11 and 13-15</u> is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10)⊠ The drawing(s) filed on <u>11 March 2004</u> is/are: a | | b by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| ·— ·— | a) All b) Some * c) None of: | | | | | | |
| | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| coo the attached detailed emice detail for a liet of the continue copies het received. | | | | | | | |
| Attach manut/a) | | | | | | | |
| Attachment(s) 1) X Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | | |
| 3) Notice of Informal Patent Application 5) Notice of Informal Patent Application | | | | | | | |
| Paper No(s)/Mail Date <u>9/13/2006; 8/25/2006</u> . 6) Other: | | | | | | | |

Art Unit: 3737

Response to Arguments

1. Applicant's arguments filed August 25, 2006 have been fully considered but they are not persuasive.

- 2. In response to arguments regarding claim 1 directed to MR imaging using a hyperpolarized liquid MR imaging agent wherein spectral-spatial excitation is used in combination with FISP or PSFI pulse sequence with flip angle of 45 to 90 degrees, Examiner notes that the most recently submitted claims filed on August 25, 2006 do not recite any such amendment to claim 1. Furthermore, none of the claims recite the specifics of the FISP or PSFI pulse sequence comprising a flip angle of 45 to 90 degrees.
- 3. In response to Applicants' argument that Driehuys et al. (6,491,895) does not teach or disclose FISP or PSFI, Examiner notes that the previously filed Office Action did not suggest that Driehuys et al. taught this limitation. This limitation is taught by the combined invention of Driehuys et al. in view of Mugler, III et al. (see previously file rejection).
- 4. In response to Applicants' argument regarding common assignment of the Driehuys et al. invention as related to the invalid use of 35 U.S.C. § 103(c), Examiner notes that the pregrant publication (US 2001/0000727) of Driehuys et al., which discloses the same exact information as the granted patent, existed at least a year prior to the priority date of the instant application. Therefore, Driehuys et al. may be applied as both a 35 U.S.C. § 102(b) and 35 U.S.C. § 102(e) reference. Application of 35 U.S.C. § 102(b) enables the use of Driehuys et al. (6,491,895/ US 2001/0000727).

Art Unit: 3737

Therefore, the rejection is maintained.

DETAILED ACTION

Information Disclosure Statement

5. The Information Disclosure Statements (IDS) submitted on September 13, 2006 and August 25, 2006 are in compliance with 37 CFR 1.97 and 1.98. The references therein have been considered.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claim is dependent from a cancelled claim (see claim 3) and therefore has no specific and substantial asserted utility.

Claim 14 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

Art Unit: 3737

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 9. Claims 1, 2, 5-11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Driehuys et al (US 6,491,895/ US 2001/0000727).

Driehuys et al anticipates all claimed features in claims 1, 2, 5-11 and 15.

Claim 1 and 15: Driehuys et al discloses a method of contrast enhanced magnetic resonance imaging (MRI) of a sample where the method comprises the steps of administering a hyperpolarized MR contrast agent having non-zero nuclear spin nuclei into said sample (the sample in Driehuys et al is a patient) for fluid dynamic investigations of the vasculature (col. 3, lines 37 - col. 4, line 15), exposing said sample or part to the sample to radiation of a frequency selected to excite nuclear spin transitions in said nuclear spin nuclei (col. 6, lines 35-49), and detecting MR signals from said sample using MR pulse sequence method (col. 4, lines 47-58).

Claim 2: Driehuys et al disclose that the contrast agent is administered to investigate the blood flow or vasculature of the patient, which is a definition of angiographic investigation (col. 4, lines 40-45). Driehuys et al also disclose that the pulse sequence is gated to the cardiac volume out cycle, which is the image acquisition

Art Unit: 3737

is gated to the cardiac rhythm (col. 13, lines 44- 54; col. 15, line 57-col. 16, line 16; col. 13)

Claim 5-11: Driehuys et al further disclose the above method where the hyperpolarized agent includes from the group consisting of ¹H, ³He, ³Li, ¹³C, ¹⁵N, ¹⁹F, ²⁹Si, ³¹P and ¹²⁹Xe.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 3, 4, and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Driehuys et al as applied to claim 1 above, and further in view of Mugler, III et al (US 5,245,282/ US 2001/0000727).

Driehuys et al substantially disclose all claimed features in claims 3 and 4 as described above. However, Driehuys et al do not teach the use of steady state imaging such as FISP or PSIF. In state of the art in magnetic resonance imaging, the use of FISP or PSIF for steady state imaging is well known to compensate for the flow or motion of the blood in blood vessel (see Mugler, III et al., col. 1, line 56 - col. 3, line 29). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Mugler, III et al's steady state

Art Unit: 3737

imaging such as FISP or PSIF to compensate for the motion as encountered in Driehuys et al's method with hyperpolarized administered to the patient's circulation system.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Driehuys et al as applied to claim 1 above, and further in view of Golman et al. (WO 9924080).

Golman et al. teach an imaging agent comprising a compound selected from either Glutamine or pyruvate (see p. 15-16).

It would have been obvious to one of ordinary skill in the art to include imaging agent comprising a compound selected from either Glutamine or pyruvate in the invention of et al in light of the teaching of Golman et al in order to enhance the utility of application of the method.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRYSTAL I. LEACH whose telephone number is (571)272-5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/ Supervisory Patent Examiner, Art Unit 3737

CIL /Crystal I Leach/ Examiner, Art Unit 3737